EXHIBIT 20

CardinalHealth

Suspicious Order Monitoring

QRA's Processes and the ISF

INTERNAL USE ONLY

Facilitator Guide (180 Minutes)

The safety and security of our nation's pharmaceutical supply chain is a top priority for Cardinal Health and a responsibility we take very seriously. A safe and reliable drug supply is central to our customers' businesses and critical to the health and well-being of their patients. We believe that we must work together with our customers to ensure that they have an adequate supply of controlled substances to meet the legitimate needs of their patients while addressing the societal issue of prescription drug abuse.

Creation date: March 2014

Updated: _____

MATERIALS CHECKLIST

____Facilitator Guide

____Participant Guides

____PowerPoint - QRA Process ISF 2014-Mar.pptx

____Three videos (Launch in PowerPoint. Files must be in same computer folder as ppt.)

1. DrugDealer.mpg
2. Pills.mpg
3. News Report v2 CS Shortage HD.wmv

____Overhead projector

____Speakers to plug into Facilitator's laptop

____Flip charts and markers

____Laptops – All facilitators and participants

FACILITATOR NOTE (15 Minutes)

- INTRODUCTION - THE PROBLEM
- OBJECTIVES

- **Slide 1** of the PowerPoint: Title *** Please indicate to all participants that these training guides are Internal Use Only. All customer facing materials can be found on the ISF Portal. Customer specific information in WinWatcher that can be shared with customers is discussed in the course.***
- **Slides 2, 3 and 4**
  1. Slide 2 is "Drug Dealer" video, 40 seconds
  2. Slide 3: Ask learners to respond before clicking for slide animation
  3. Slide 4: Follow up to slide 3

- **Slide 5: Read or have a learner volunteer to read the objectives** (See page 2 of Participants' Guide)

INTRODUCTION (Participant Guide page 2)

The problem…

A team discussion.

OBJECTIVES

Performance Objectives

Learners will be able to perform the following after completing this training module:

- Describe the problem of diversion of pharmaceuticals
- Explain Cardinal Health's obligations under the Controlled Substances Act and accompanying regulations
- Explain Cardinal Health's enhanced Suspicious Ordering Monitoring Program.
- Explain anti-diversion responsibilities of the ISF
- Utilize WinWatcher QRA reports for territory management responsibilities

FACILITATOR NOTE- INTRODUCTION - *Continued*

- **Slides 6 and 7**
  1. Slide 6: Discussion of Cardinal Health's responsibilities and the responsibilities of our employees.
  2. Slide 7: Note that all CAH sales and operations employees must help Quality and Regulatory Affairs in their efforts.

- **Slide 8 thru 11**
  - Slide 8: Have learners attempt to identify the prescription drugs
    - Click PPT for
    - 1st, Prescription painkillers (e.g., OxyContin and Vicodin)
    - 2nd, Sedatives/tranquilizers (e.g., Valium & Xanax)
    - 3rd, Stimulants (e.g. Ritalin & Adderall)
    - **Say**: These are most prone to abuse.
  - Slide 9: **Say**: These 13 drug families are closely monitored by QRA
    - Alprazolam, hydrocodone and oxycodone are MOST closely monitored
    - Of those alprazolam **2 milligram**, hydrocodone **10 mg** and oxycodone **15 mg** and **30 mg** are **most closely monitored within those families**.
      - **Say:** We'll discuss these specific drug strengths later in this session.
      - **Note:** List of 13 families found at ISF Portal > Training tab > QRA Information section, QRA FAQs.
  - Slide 10 is "Pills" video, 40 seconds
  - Slide 11: Further commentary on extent of the societal problem of prescription drug abuse.

TRANSITION

Say: Now let's discuss what our QRA team is doing, together with us in the field, to reduce the problem.

FACILITATOR NOTE (10 Minutes)

THRESHOLD LIMIT METHODOLOGY

- **Call Outs**
  1. Whether the purchase method or the preferred dispensing data method is used, the methodology is not "one-size-fits-all", QRA considers other factors specific to the pharmacy.
  2. An FAQ below states that customer provided usage history is NOT considered during any part of the threshold setting or changing processes. A QRA field investigator may ask a customer for this report during a site visit. However, the sales force should not submit this data to QRA.

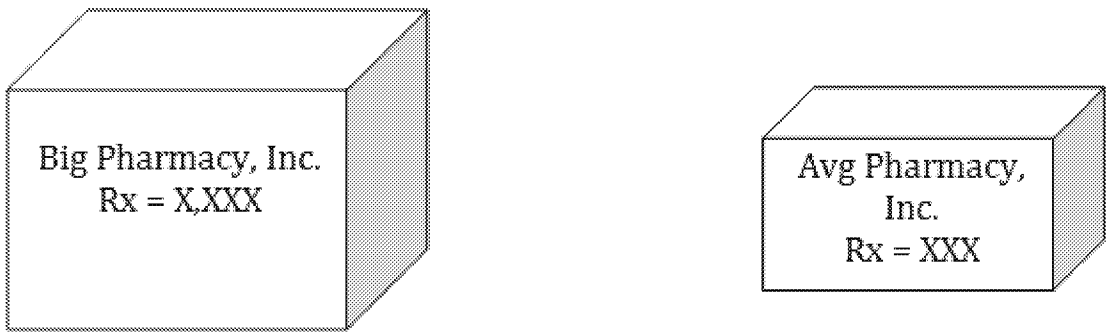
THRESHOLD LIMIT METHODOLOGY (Participant Guide page 3)

We have established objective criteria to help us identify ordering patterns similar to pharmacies that have been the subject of adverse Drug Enforcement Administration (DEA) actions. Pharmacies with different prescription volume have different needs, but most tend to align with average usages of controlled substances relative to all their overall prescriptions.

Pharmacy Threshold Limits

Go to Slide 12

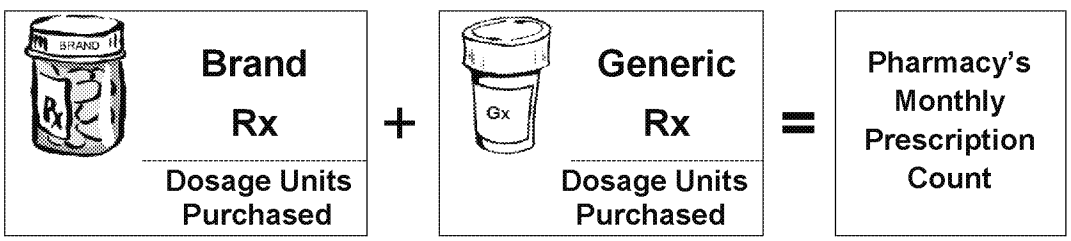
Prescription count serves as the foundation.



► A pharmacy that fills 1000 prescriptions per day requires more prescription drugs – and more controlled substances – than a pharmacy that fills 100 prescriptions per day.

Go to Slide 13

For many customers we have limited visibility into the number of prescriptions they fill. In these situations, we calculate a prescription count based on the customer's purchases from us, accounting for pricing of generic and brand drugs.



FACILITATOR NOTE: Throughout the course booklet look for the "?" icon. These are from the FAQs responded to by QRA senior leadership. Additional FAQs can be found on the ISF Portal > Training tab > QRA Information section.

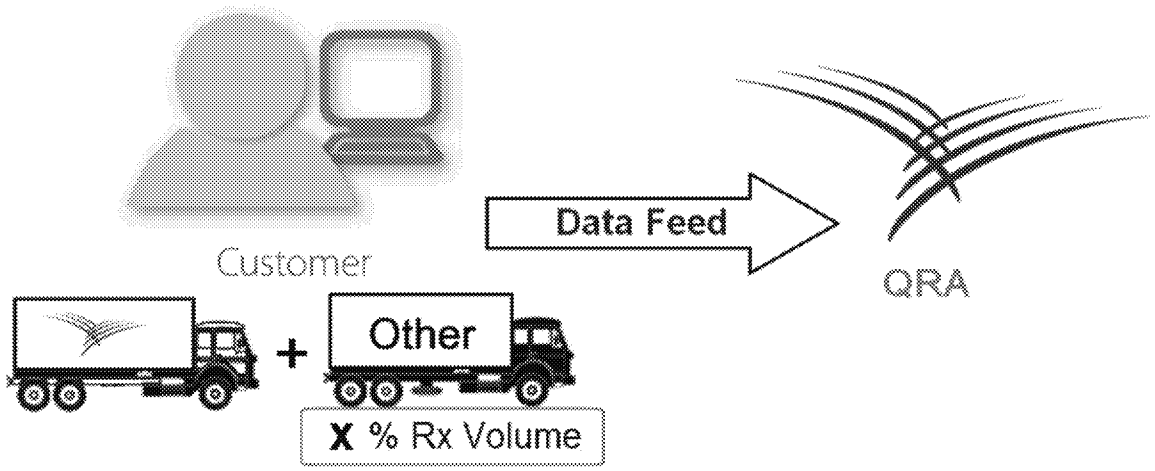
Is customer provided usage history considered during any part of the threshold setting or changing processes?

► No. We no longer use customer provided usage history.

FACILITATOR NOTE: Two more call outs:

- **If questioned is asked, *Q*:** *"If we get their dispensing data, can we precisely calculate prescription volume?"* ***A:*** *"We take a conservative approach. Dispensing data may not be fully accurate. For example, some pharmacies have more than 1 switch and we are not getting the data for both. Also, we would be less aware of cash sales that are not adjudicated to a cash bin."*
- Emphasize that the CAH associate must explain to customers that (as stated below): "…if they purchase the same controlled substance drug family from another distributor we may further reduce their threshold and we may refuse to sell them some or all controlled substances."

► However, if Cardinal Health has visibility into a customer's prescription volume …



The data feed option provides visibility into a customer's prescription dispensing volumes.

With a data feed we give customers 50 percent credit for the prescription volume associated with purchases from other distributors.

Cardinal Health can receive dispense data for a customer via a switch data feed release

and Business Associate Agreement or through one of the following solutions: Cardinal Health Inventory Manager, Reimbursement Consulting Services, and certain customers using Reconciliation.

► Be sure customers also understand that if they purchase the same controlled substance drug family from another distributor we may further reduce their threshold and we may refuse to sell them some or all controlled substances. According to the DEA, purchasing the same controlled substances from more than one source is a pattern displayed by pharmacies that dispense controlled substances for other than a legitimate medical purpose.

Recapping

Part of our efforts to continuously improve our anti-diversion program is an enhanced threshold-setting methodology. Prescription count serves as the foundation of our methodology. This ensures that the volume of controlled substances we distribute to a customer is justified by their prescription volume.

The more data we have, the more accurate the prescription count will be. Whether from Cardinal Health purchases, or from dispensing data, this new method ensures that our distributions of controlled substances to our customers make sense based on our knowledge of each customer.

FACILITATOR NOTE (10 Minutes)

Go to Slide 14 (Attention: You will not use the PowerPoint again until near the end of the session in the "Pharmacist's Corresponding Responsibility" section.)

Review the content:

Customer Facing Communication

- You may point out that the approved customer facing document, as a leave-behind, does not include the column with the 95% percentile information.

Objective Criteria

- Discuss the national averages
- Don't get engaged in a "debate" with a customer over the statistical methodology.
- A sales associate should not attempt to tell a customer what percentages their pharmacy is allowed. QRA takes other factors into consideration for threshold setting.
- Approaching or exceeding the 95th percentile subjects the customer to "additional scrutiny" by our QRA department.

Objective Criteria Talking Points

- This document points out the need for a pharmacy to be aware of their risk.
- It also points out questions a pharmacy owner/manager should ask themselves to assess if they are at risk of being scrutinized by the DEA or state regulators.

CUSTOMER FACING COMMUNICATION (Participant Guide page 6)

CardinalHealth
Essential to care™

Enhancing our anti-diversion program

March 27, 2013

The safety and security of our nation's pharmaceutical supply chain is a top priority for Cardinal Health and a responsibility we take very seriously. A safe and reliable drug supply is central to our customers' businesses and critical to the health and well-being of their patients. We believe that we must work together with our customers to ensure that they have an adequate supply of controlled substances to meet the legitimate needs of their patients while addressing the societal issue of prescription drug abuse.

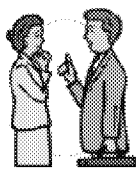
We have established objective criteria to help us identify ordering patterns similar to pharmacies that have been the subject of adverse DEA actions. Pharmacies with different prescription volume have different needs, but most tend to align with average usages of controlled substances relative to all their overall prescriptions.

Eight objective criteria	National average[1]
1. The percentage of oxycodone that is oxycodone15 and 30 milligram products	22%
2. The percentage of hydrocodone that is hydrocodone10/325 milligram products	33%
3. The percentage of alprazolam that is alprazolam 2 milligram product	16%
4. The percentage of prescription drug dosage units that is controlled substances	21%
5. The percentage of all prescriptions that is oxycodone and hydrocodone prescriptions	4.5%
6. The percentage of controlled substance units dispensed that is an ADD/ADHD drug (i.e., amphetamine and methylphenidate)	7%
7. The percentage of controlled substance units dispensed that is a benzodiazpine (e.g., alprazolam, diazepam, midazolam, etc.)	20%
8. The percentage of all prescription drug dosage units dispensed that is an opiate (e.g., hydrocodone, oxycodone, methadone, morphine, oxymorphone, etc.)	13%

[1] *We base these figures on established data sources and/or industry benchmarks.*

You are encouraged to use this in conversation with customers. You can find this document on the ISF Portal > Training tab > QRA Information section link: Understand the Objective Criteria – for customers.

► The pharmacy can assess their risk by being aware of how they compare to these objective criteria.



"Knowing where you are relative to these averages will help you identify if your pharmacy's ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions."

FACILITATOR NOTE: Throughout the course booklet, look for areas within the text that appear as [learners write in this information]. In the Participants' Guide it will look like _____. This is to encourage them to follow the discussion closely, to stimulate thought about the point being emphasized, and help with learning retention. It is important that you go through your printed Facilitator Guide before hand, be aware where these are, and use highlighter or Post-It notes in the margins to get **your** attention. Of course, be sure to specifically review these points during your summation.

Objective Criteria

Using the customer facing document, talk with customers about the objective criteria to ensure that they understand that their controlled substance orders are being compared to these [**national averages**].

From the Internal Use Only document *Understand the Objective Criteria (March 27, 2013)* we know that,

> "Part of our efforts to continuously improve our anti-diversion program is an enhanced threshold-setting methodology. Our scoring system uses the [eight] objective factors … to calculate a customer's score and pass/fail rating. This pass/fail rating will determine whether or not, and to what extent, we set thresholds above the national average.
>
> Customers whose objective scores approach or exceed the 95th percentile in one or more of these areas as well as customers with a high cumulative score for the eight factors will receive [**additional scrutiny**] and thresholds will be managed accordingly.
>
> We established objective criteria to help identify those pharmacies whose ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions."

Objective Criteria Detail Report

The pass/fail rating is an [**internal QRA calculation**], however, you can see the score for each of your customers in WinWatcher's Objective Criteria Detail Report. Note that the method is intended to *"help identify those pharmacies whose ordering patterns are similar to pharmacies that have been the* [***subject of adverse DEA actions.**"*] Distributors are required to detect suspicious orders for controlled substances and inform the DEA of suspicious orders in accordance with 21 C.F.R. section 1301.74(b). Suspicious orders are

"orders of [**unusual size**], orders [**deviating substantially from a normal pattern**], and orders of [**unusual frequency**]."

The Internal Use Only document *Understanding Your Customers' Objective Criteria Score Numbers* indicates this report lets you see how a customer compares to the national averages. The further the customer is above the national average, the [**higher their score**]. **You should discuss this with your customers.**

Objective Criteria Talking Points

From the Internal Use Only document *Objective Criteria Talking Points (April 2013)* we are provided the following guidance:

> "Begin your conversations with an emphasis on the need to ensure the safety and security of the pharmaceutical supply chain. Don't allow the conversation to be derailed by discussions of DEA actions and our distribution centers.
>
> The pharmacy can assess [**their risk**] by being aware of how they compare to these objective criteria.
>
> In recent years, DEA has increased the number of administrative actions against pharmacies with a focus on ensuring that [**pharmacists**] are fulfilling their [**corresponding responsibility**] when filling controlled substance prescriptions. Pharmacists who will be interviewed by DEA or state regulators may be asked to address the following types of questions:
>
> - If the pharmacy dispenses any controlled substances, but particularly if the amount of controlled substances dispensed is above the average, is the pharmacist confident that the volume is the result of the prescriptions for those controlled substances that have been issued for a [**legitimate medical**] purpose and in the normal course of professional practice?
>
> The pharmacist, whose pharmacy dispenses above the national averages, should also consider assessing those prescribers (e.g., physicians, nurse practitioners, physician assistants, etc.) for whom they fill prescriptions.
>
> Anticipate customer push backs such as, "We check all controlled substance prescriptions carefully.", or "We're not a pill mill."
>
> - "Knowing where you are relative to these averages will help you identify if your pharmacy's [**ordering patterns**] are similar to pharmacies that have been the subject of adverse DEA actions."
>
> - Alert pharmacy customers to the importance of their assessing the [**legitimacy of the prescriptions**] they receive and simply not relying on the fact that a prescriber they may or may not recognize, wrote the prescription for a patient and that the prescriber has a valid DEA registration.

- Pharmacists should assess both the professional [**risk**] to their license and the [**risk**] to their business by filling prescriptions for a high controlled substance prescriber that the pharmacist may not be familiar with.

- The question a pharmacist should ask themselves is: "If you don't know the prescriber and their practice well, is the profit in those prescriptions worth the [**risk to his or her business**]?"

You should also refer to the Pharmacist's Corresponding Responsibility White Paper and the one pager entitled "Top 10 Questions pharmacists should ask when filling Controlled Substances" on the ISF Portal in the News and Communication section for more information and talking points. (A copy of *Top 10 Questions* is in these booklets as an appendix.)

Where are we getting the national average referred to in the January 23, 2013 communication? Is the 95th percentile based on the national average or Cardinal Health customers?

▶ The information used in our threshold setting methodology comes from IMS data, the DEA, our own internal sales and customer dispensing data. The 95th percentile is based on both the national average and the averages for Cardinal Health customers.

FACILITATOR NOTE: (20 Minutes)

Role Play: Explain Cardinal Health's SOM Threshold Setting

Before looking at specific customer data found in WinWatcher, confirm that team members can explain the basics of our methodology to customers.

- Using the customer facing document *Enhancing Our Anti-Diversion Program* above, have one or more team members explain our Suspicious Order Monitoring process to a customer in a role play.
  - This role play is not intended to have the PBC deal with a lot of push-backs or arguments. The purpose is to see if they can convey the information accurately and clearly.
  - In the Guides is a scripted role play. Use this as a basis for discussion afterwards.
- Before selecting the team members for the role play, give the entire team 10 minutes to review the materials above.
- After each role play discuss as a group key points that were made and suggest others that might help prepare for the actual conversations in the field.

Role Play: Explain Cardinal Health's SOM Threshold Setting (Partic. Guide page 9)

- Pharmacist – This pharmacist just started working for a current CAH customer. Besides dispensing and patient counseling duties, this pharmacist will have management responsibilities including purchasing.
- PBC – Has called on the pharmacy for a long time. Knows that the pharmacy is providing dispensing data because they are on Reimbursement Consulting Services.

Pharmacist: How do you decide how much I can purchase of controlled substances per month?

PBC: It begins with your script count. A large pharmacy needs more of everything than a medium or small size pharmacy does.

We also have national averages for controlled substance dispensing. Here, let me show you what we call the Objective Criteria. On average 21% of the prescriptions dispensed by a retail independent pharmacy are controlled substances. Also, on average, 4.5% of all the scripts dispensed are oxycodone and hydrocodone. And you can see the other criteria here on this document.

Pharmacist: So if the average pharmacy is dispensing 10,000 pills of a certain drug and my store does more business than the average I get more than 10,000 of that drug?

PBC: Yes, basically, because it should be in proportion to the non-controlled prescription drugs. Of course our Quality and Regulatory Affairs team takes other factors into consideration for threshold setting.

And, our QRA folks look closer within certain drug families. Let say that 10,000 is your hydrocodone dispenses. We also have a national average that says 33% (pointing to the customer facing document.) is typically the 10mg strength. That's because those tend to be more commonly abused. So higher than one third of the hydrocodone 10mg is a signal to the analysts that the pharmacy is running a higher risk.

Pharmacist: Averages can be way off. You take a high number and a low number and you get an average. In a sense you can say no pharmacy is average.

PBC: QRA recognizes that. They look at where a store is at compared to the average and compared to the 95 percentile. That allows for variances from month to month or from store to store.

Pharmacist: Okay, so do I give you a dispensing report and you figure out my script count.

PBC: We don't use the dispensing reports. The best method is to look at your dispensing data from your switch. With that we can calculate your script volume. The more data we have, the more accurate the prescription count will be.

Pharmacist: I'm curious, what if I'm the owner and I didn't give you access to my dispensing data?

PBC: Then we look at what you purchase from us. Knowing your cost for brand drugs and your cost for generic drugs we calculate a script count.

Pharmacist: Yeah but everyone buys something outside of their primary wholesaler. You don't see those purchases.

PBC: Yes, that's right. Those dollars aren't accounted for. If it's only a small amount it won't have a big impact. But we will only base our thresholds setting on what we know about your pharmacy. We take our societal responsibilities to help prevent drug diversion and abuse very seriously, and so, we will calculate the threshold amounts based only on the information we have.

Pharmacist: So do you tell me what my threshold limits are?

PBC: Yes. And also I'll keep you informed of how your percentages compare to these averages.

Knowing where you are relative to these national averages will help you identify if your pharmacy's ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions.

If you are way above average there should be a legitimate reason for it. We feel it is in your best interest to look at your pharmacy operations and try to determine why sales of controlled substances would be high compared to all your prescriptions.

~ ~ ~ ~ ~ ~

FACILITATOR NOTE (10 Minutes)

Review the content:

"Sub-base Code" Thresholds

- The Zohydro sub-base codes were added for all customers in March 2014. They were added because of the potential for abuse as the initial product to hit the market is without an abuse resistant delivery form.
- For the levels that oxycodone and hydrocodone sub-base thresholds are set at, see the FAQ below. For Zohydro see the FAQs on the ISF Portal.
- Requests to QRA for adjustments are discussed later. However, point out the statement below: " sub-base code thresholds will not be adjusted independent of a threshold adjustment for the drug family."

What else can be shared with customers?

- Sales should discuss the thresholds with customers. Encourage customers to keep you

informed so you can proactively communicate with the QRA Customer Analytics team.

"Sub-base Code" Thresholds (Participant Guide page 11)

Sub-base code thresholds are separate thresholds **within a drug family** for certain drug products that are more susceptible to [**diversion**] and [**abuse**].

- Oxycodone 15 and 30 milligram immediate release products
- Hydrocodone 10 milligram products
- Zohydro ER 10mg, 15mg and 20mg products; and 30mg, 40mg and 50mg products

One of the recurring ordering patterns among pharmacies that have been recently shut down by the DEA is that certain drugs strengths of concern constitute the majority of the orders for that particular drug family.

For example, in many cases oxycodone 15 and 30 milligram products when combined comprised the majority of the oxycodone ordered.

In response to this, we have established separate thresholds within a drug family for certain drug products that are more susceptible to diversion and abuse. These are "sub-base code" thresholds. They could have a significant impact on those customers whose orders for oxycodone or hydrocodone are primarily comprised of drug strengths of concern.

What are the sub-base code thresholds for the thirteen (13) drug families of the greatest concern?

There are sub-base code thresholds in place for all customers for the oxycodone drug family. These sub-base codes are set to no more than 50% of the overall oxycodone drug family threshold. For example, if a customer has an oxycodone threshold of 10,000, it will have a sub-base code threshold, specific to the 15mg/30mg single strength immediate release product, of 5,000 or less.

Most customers have been reviewed and had their hydrocodone 10mg sub-base code established for combination products (e.g., hydrocodone with acetaminophen or ibuprofen). If a customer has had a hydrocodone sub-base code threshold put into place, this has been communicated to the PBC.

► It is important to note that sub-base code thresholds will not be adjusted independent of a threshold adjustment for the drug family.

What else can be shared with customers?

PBCs should be sharing with customers their

- Monthly threshold limits

- Their accrual amounts
- Explaining the percent of monthly completion
- Objective Criteria Detail Score

on a regular basis.

All of this information is found in WinWatcher on the Customer 360 Regulatory Tab and the QRA Threshold Awareness Detail territory report. These conversations will facilitate a dialog around a customer's purchase needs and should undercover information that could be provided to the Customer Analytics team and possibly warrant a threshold increase proactively.

Can I leave behind threshold numbers with a customer?

► All Customer 360 Regulatory Tab information in WinWatcher can and should be shared with customers. However, good judgment should be used regarding leaving behind hard copies of this information.

FACILITATOR NOTE: (25 Minutes)

WINWATCHER QRA REPORTING
Test Yourself (Participant Guide page 13)

- 5 Minutes: Have learners individually complete the quiz
- (All the information can be found in the ISF Portal > Training > WinWatcher > WW QRA Chapter)
- **Review the content** that follow to provide the answers to the quiz.
- Facilitator's Guide WinWatcher quiz information:
  - The correct answers to the True/False quiz are highlighted in gray.
  - Each section that deals with these WinWatcher quiz questions will be marked in the section header, e.g., **(WW Quiz Question #1)**.
  - The specific answer is **numbered, underlined and in bold** in both Facilitator and Participants' Guides.

WINWATCHER QUALITY AND REGULATORY AFFAIRS REPORTING

WinWatcher provides Quality and Regulatory Affairs (QRA) reports and tools which can be accessed at the individual and the team level based on the user's relationship to direct reports and their WinWatcher access authority. These reports and tools will enhance the ability of the sales force to know their customers and detect indications of drug diversion.

CardinalHealth

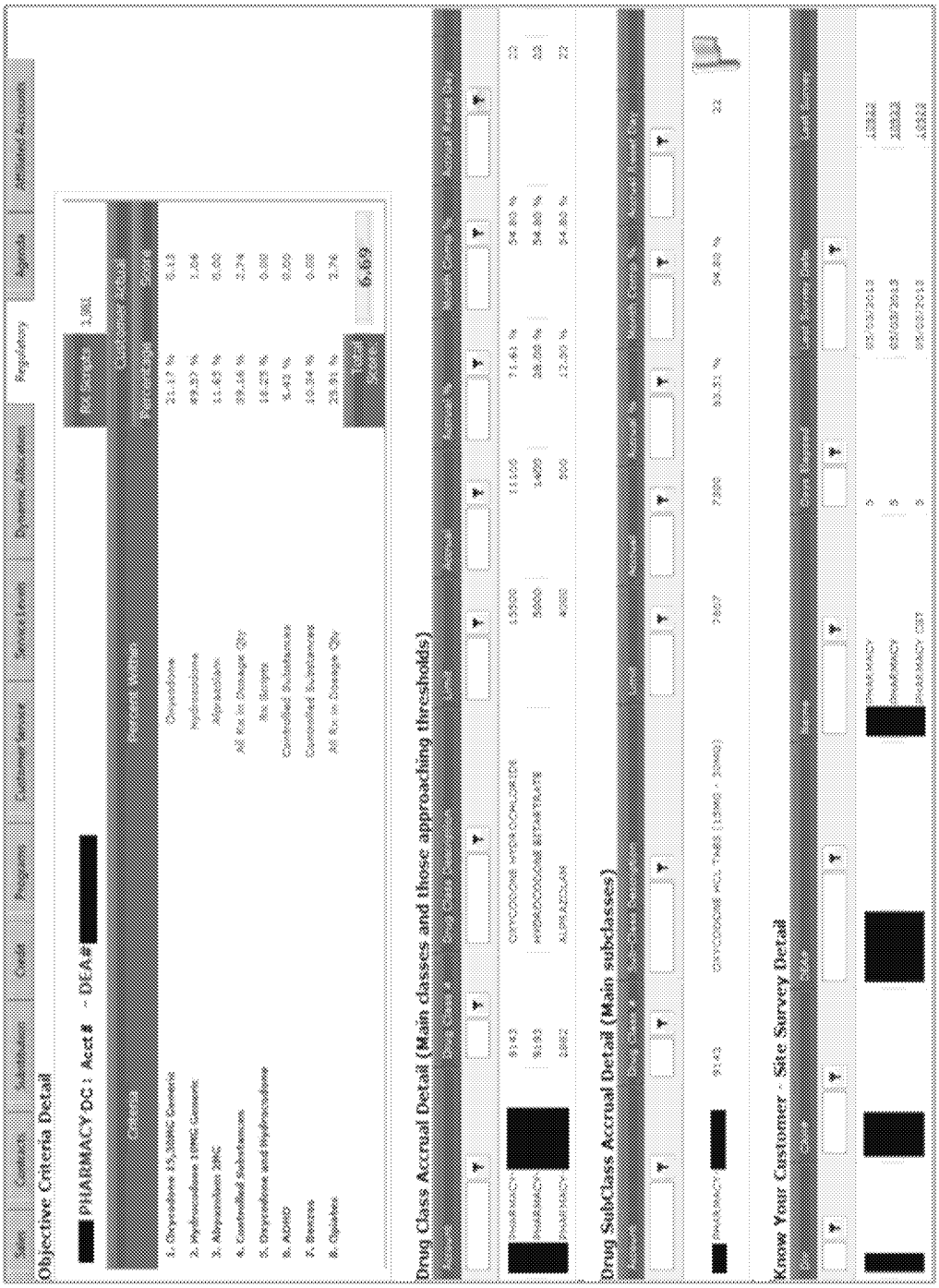
Pharmaceutical Distribution - Sales Training & Operations

SOM – QRA Process (Internal Use Only)

Test Yourself – Individually complete the following quiz.		Circle the answer
1.	True or False. The QRA threshold limits and accruals cannot be viewed on the mobile version of WinWatcher, therefore, you must always check the information on your laptop before a sales call.	True False
2.	True or False. It's 12 days after a customer's accrual cycle has started. Their oxycodone limit is 12,500 and the accrual is 9,000. Their hydrocodone limit is 18,500 and the accrual is 14,800.There is no reason to discuss this with the pharmacy.	True False
3.	True or False. Accruals are the amount in dosage units that the customer has ordered since their accrual reset date. Accruals may include product ordered but not shipped.	True False
4.	True or False. WinWatcher users can see all of the details for customers in their territory who are hitting an awareness flag in one report so they don't have to review the accrual per threshold flag one by one in the Customer 360 Regulatory tab.	True False
5.	True or False. The alprazolam, hydrocodone and oxycodone drug families will always display the threshold limit and accrual in WinWatcher even if the customer's accrual is not running ahead of the amounts expected for the number of days that have elapsed in their accrual period.	True False
6.	True or False. You can immediately see your customers' threshold limits and accruals for all thirteen closely monitored drug families.	True False
7.	True or False. Because sub-base code drugs are more susceptible to diversion and abuse their thresholds are never visible in WinWatcher.	True False
8.	True or False. The QRA threshold limits and accruals shown in WinWatcher cannot be revealed to customers.	True False
9.	True or False. Because customers' monthly Rx Scripts volume calculated by QRA is not displayed in WinWatcher you will need to contact QRA for that script count.	True False
10.	True or False. The Customer Actual Percentages and Scores in the WinWatcher Objective Criteria Detail report are for use by the Customer Analytics team. You do not need to discuss these percentages and scores with customers.	True False
11.	True or False. If you receive an email assigning a mandatory QRA sales site survey you have five (5) business days to complete the survey.	True False
12.	True or False. The magnifying glass icon from the Pharmacy Finder search, from mobile and from PC WinWatcher Survey Account Detail report will launch the QRA sales site survey so you can submit a proactive survey.	True False

Customer 360 Regulatory Tab – (WW Quiz Question #1)

You can view your customer's controlled substance thresholds, accruals and additional information on the Regulatory tab of the Customer 360 page. The information, except the Objective Criteria Detail, (#1) **can also be viewed in the WinWatcher mobile version**.



QRA Territory Reports – (WW Quiz Question #2, #3, #4)

FACILITATOR NOTE QRA Territory Reports

After a brief review of the content and quiz questions, have learners log into WinWatcher

- Access the QRA Awareness Flag Territory Report
  - Hover over myHomePage button
  - Hover over "QRA"
  - Click on "QRA Threshold Awareness Detail"
- **NOTE**: If your DC's Accrual Reset Day has just occurred there may be very few accounts on the PBCs' reports.
- Call on your PBCs to interpret their report.
- **As they interpret their report they are to write in the answers to the list of questions:**
  - After giving learners a few minutes to complete the questionnaire, use the questions as discussion points.

Territory Planning

Territory planning is imperative in order to sustain momentum towards your goals in the face of the daily demands of servicing your customers. An important tool for managing the SOM responsibilities of your job is the **QRA Threshold Awareness Detail** report found in WinWatcher.

The intent of this report is to assist sales consultant monitor the accruals of their customers' controlled substances.

The best practice for use of the report is to access it periodically throughout the week and consider what customer interaction must occur.

- Look for customers on the report who are over 100% accrual?
  - Have I communicated with the customer and the Customer Analytics team?

- **(#2) Which customers are approaching their threshold for a drug family, or families, faster than their monthly accrual period is passing?**
  - Have I discussed this with the customer?
  - What information has the customer provided?
  - Does the information warrant a request to the QRA Customer Analytics team to assess whether or not the customer's threshold limit should be increased?

Monthly Completion %	Accrual to Threshold %
<= 25%	>=50%
> 25% And <=50%	>=75%
>50%	>=90%
Criteria to generate a customer Awareness Flag	

(#3) Accrual is based on what is ordered. Unshipped product adds to a customer's accrual.
In the eyes of the DEA the purpose of suspicious order monitoring is identifying an order, not a shipment, of unusual size, frequency or pattern.

The WinWatcher QRA Threshold Awareness Detail report can be accessed from a personal computer or a mobile device. Only customers whose accrual(s) meet or exceed the criteria to generate an Awareness Flag appear on the report. **(#4) Each Pharmacy Business Consultant views their own customers and managers can see their entire team's customer information.**

Using the Report

PBCs should be sharing with customers their monthly threshold limits, their accrual amounts, and explaining the percent of monthly completion on a regular basis. All this information is found in WinWatcher on the Customer 360 Regulatory tab.

It's important that this occurs on a regular basis, ideally before your customer has a threshold event or is trending above their expected accrual.

These conversations will facilitate a dialog around a customer's purchase needs and should undercover information that could be provided to the Customer Analytics team and possibly warrant a threshold increase proactively.

Objective Criteria Detail Report

After checking the WinWatcher QRA Threshold Awareness Detail report, run the Objective Criteria Detail report. Check the Total Score column. For customers with relatively high total scores, that are in your upcoming sales call route, add this as an agenda item to discuss.

The Objective Criteria Detail report is discussed in detail below.

CardinalHealth

Pharmaceutical Distribution - Sales Training & Operations

SOM – QRA Process (Internal Use Only)

(Participant Guide page 17)

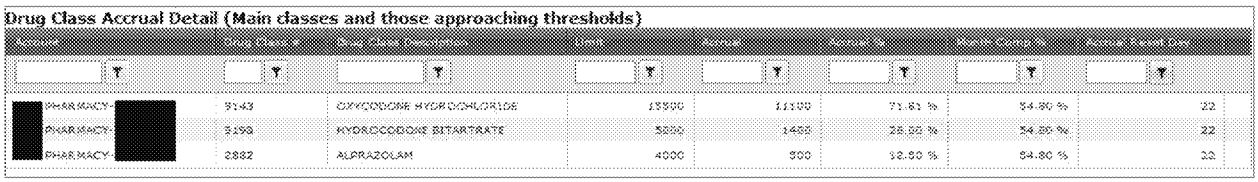
Log into WinWatcher • Access the QRA Threshold Awareness Detail report • Complete this questionnaire
1. For the pharmacies on your report, have you already discussed our SOM program, and the national averages they are compared to?
2. For the pharmacies on your report, have you made them aware that they should keep you informed of any changes to their business model that may change their prescription volume, particularly if controlled substances may increase disproportionately?
3. For the pharmacies on your report, have you shared with them what their threshold limits are?
4. Have you explained to all these customers their accrual reset day?
5. Are you using this report on a regular basis, and for the customers that appear are you adding to your sales call agenda a notation to discuss these accruals and Awareness Flags?
6. For the customers on your report, are you confident that you have sufficiently educated them about our SOM program so that you could discuss these Awareness Flags via a phone call?
7. What about **all** your customers? If at some point they appear on the report, what would be your response to the questions above?

Threshold Limits – Main And Sub-Base (Participant Guide page 18)

You can view the thresholds of your customer's controlled substance purchases in the Regulatory tab on the Customer 360 page. Customer thresholds and their orders for a one month period are displayed.

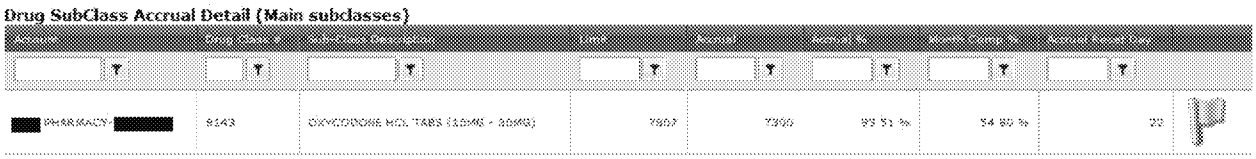
Drug Class Accrual Detail

A report of a customer's monthly threshold limits and accruals for the alprazolam, hydrocodone and oxycodone drug families and of other monitored drug families with accruals greater than the pro rata amount of their monthly limit.



Drug Sub-Class Accrual Detail

What will appear on this report of sub-base drugs with threshold limits varies by customer. See below.



What drug families appear in WinWatcher? **(WW Quiz Question #5, #6, #7, #8)**

(#5) Alprazolam, oxycodone and hydrocodone thresholds and accruals are always displayed in WinWatcher.

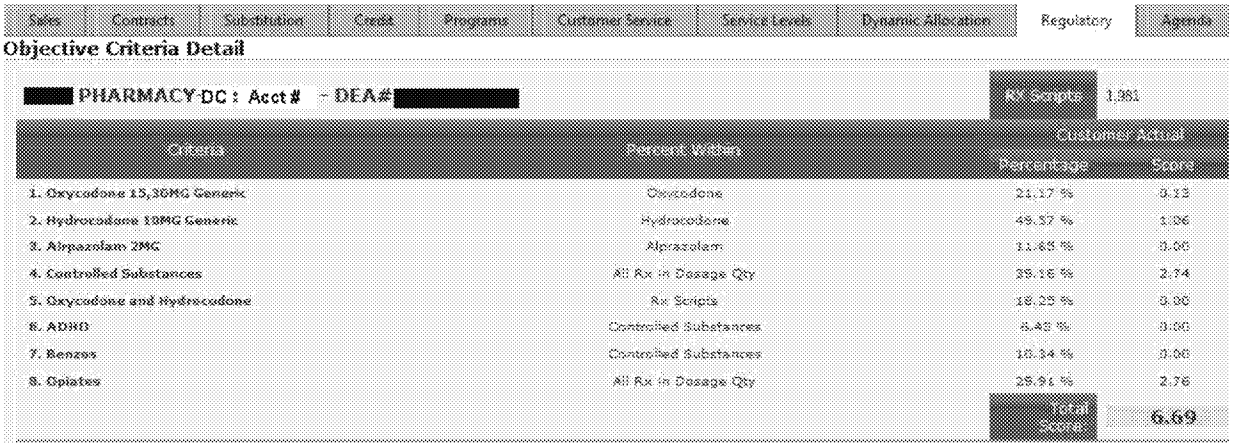
(#6) Other drug families (13 closely monitored) appear if the drug's accrual is trending above the expected accrual for the current reset month's completion percentage. See the Criteria to generate a customer Awareness Flag above.

(#7) Most customers have a oxycodone 15mg/30mg immediate release **sub-base threshold**. Some have a hydrocodone 10mg **sub-base threshold**. These will always be display. **Sub-base thresholds** of Zohydro 10mg, 15mg and 20mg products and Zohydro 30mg, 40mg and 50mg products **appear if the drug's accrual is trending above the expected accrual** for the current reset month's completion percentage..

As noted above, **(#8) all this Customer 360 Regulatory Tab information in WinWatcher can and should be shared with customers.** Let them know that pharmacies with different prescription volumes have different needs, but most tend to align with average usages of controlled substances relative to their overall prescriptions.

Objective Criteria Detail Report (WW Quiz Question #9, #10)

As discussed earlier, Rx script count for each customer is calculated either from dispensing data, or without access to that data, from their purchases from Cardinal Health. **(#9) The calculated Rx script count can be seen** in WinWatcher Customer 360 Regulatory tab, Objective Criteria Detail.



Sales | Contracts | Substitution | Credit | Programs | Customer Service | Service Levels | Dynamic Allocation | Regulatory | Agenda

Objective Criteria Detail

[redacted] PHARMACY-DC : Acct # - DEA# [redacted]

Rx Scripts: 1,981

Criteria	Percent Written	Customer Actual Percentage	Score
1. Oxycodone 15,30MG Generic	Oxycodone	21.17 %	0.13
2. Hydrocodone 10MG Generic	Hydrocodone	49.57 %	1.06
3. Alprazolam 2MG	Alprazolam	11.65 %	0.00
4. Controlled Substances	All Rx in Dosage Qty	39.16 %	2.74
5. Oxycodone and Hydrocodone	Rx Scripts	18.25 %	0.00
6. ADHD	Controlled Substances	6.40 %	0.00
7. Benzos	Controlled Substances	10.34 %	0.00
8. Opiates	All Rx in Dosage Qty	25.91 %	2.76
		Total Score	6.69

As stated in the FAQ below the scores are used by QRA in setting thresholds relative to the national averages, and high scores merit "additional scrutiny." Review the Internal Use Only document *Understanding Your Customers' Objective Criteria Score Numbers (June 3, 2013),* which also advises that **(#10) you should discuss with your customers their scores and the meaning.**

What happens if my customer fails one or more of the objective criteria? Will their ability to order controlled substances be suspended?

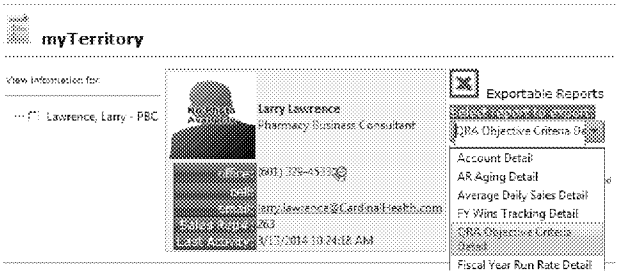
Part of our efforts to continuously improve our anti-diversion program is an enhanced threshold-setting methodology. Our scoring system uses 8 objective criteria factors to calculate a customer's score and pass/fail rating. This pass/fail rating will determine whether or not, and to what extent, we set thresholds above the national average.

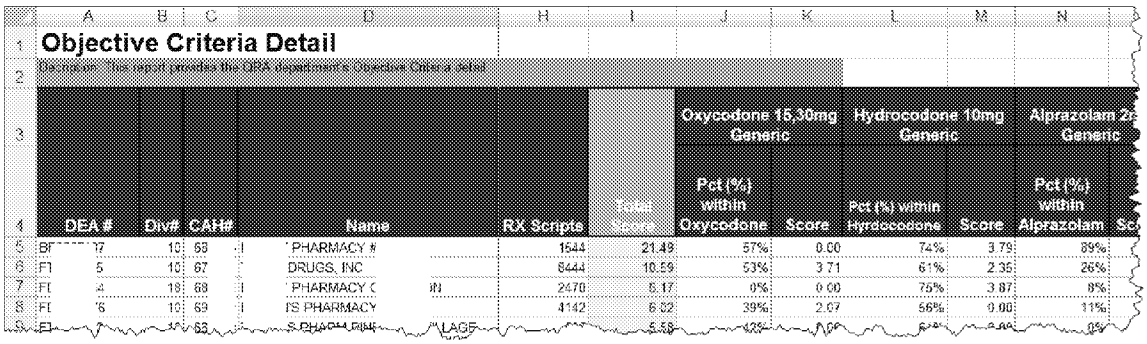
- Customers whose objective scores approach or exceed the 95th percentile in one or more of these areas, as well as customers with a high cumulative score for the eight factors, will receive additional scrutiny and thresholds will be managed accordingly.

We established objective criteria to help identify those pharmacies whose ordering patterns are similar to pharmacies that have been the subject of

adverse DEA actions. Again, in order for our assessment to be accurate, we need visibility to customers' dispensing volumes through one of our offerings or a Data Transmission Agreement. Without that information, we will use the more conservative approach of estimating prescription volume based on purchases from Cardinal Health.

Generate the report for your entire territory. As stated above, for customers with relatively high total scores, that are in your upcoming sales call route, add this as an agenda item to discuss.





Objective Criteria Detail

DEA #	Div#	CAH#	Name	RX Scripts	Total Score	Oxycodone 15,30mg Generic Pct (%) within Oxycodone	Oxycodone 15,30mg Generic Score	Hydrocodone 10mg Generic Pct (%) within Hydrocodone	Hydrocodone 10mg Generic Score	Alprazolam 2r Generic Pct (%) within Alprazolam	Alprazolam 2r Generic Sc
BF	12	10	68	PHARMACY #	1544	21.49	57%	0.00	74%	3.79	89%
FI	5	10	67	DRUGS, INC	8444	10.59	53%	3.71	61%	2.35	26%
FI	4	18	68	PHARMACY C	2470	6.17	0%	0.00	75%	3.87	8%
FI	6	10	69	IS PHARMACY	4142	6.02	39%	2.07	56%	0.00	11%
FI		10	63	S PHARM INC	LAGE	5.58	42%	0.00	64%	0.00	0%

Exported myTerritory report.

FACILITATOR NOTE (15 Minutes)

OBJECTIVE CRITERIA DETAIL

Role Play: Explain the Objective Criteria Detail Score to a Customer

- Call a team member to be the PBC and another to be a pharmacist.
- Have the PBC explain what the score of 11.98 means for their pharmacy.
  - In the Guides is a scripted role play. Use this as a basis for discussion afterwards.
- Give the PBC 5 minutes to review the material.
- After each role play discuss as a group key points that were made and suggest others that might help prepare for the actual conversations in the field.

Explaining (Participant Guide page 21)

How would you explain what the score of 11.98 means for this pharmacy?

Hint: Use a copy of the customer facing document with the national averages for the objective criteria.

Objective Criteria Detail

DRUG- : 9 - DEA#BY 98 RX Scripts 7,090

Criteria	Percent Within	Customer Actual Percentage	Customer Actual Score
1. Oxycodone 15,30MG Generic	Oxycodone	40.81 %	2.31
2. Hydrocodone 10MG Generic	Hydrocodone	79.12 %	4.35
3. Alprazolam 2MG	Alprazolam	21.98 %	0.78
4. Controlled Substances	All Rx in Dosage Qty	32.38 %	1.77
5. Oxycodone and Hydrocodone	Rx Scripts	8.19 %	1.47
6. ADHD	Controlled Substances	1.25 %	0.00
7. Benzos	Controlled Substances	22.70 %	0.00
8. Opiates	All Rx in Dosage Qty	22.07 %	1.31
		Total Score:	11.98

Role Play: Explain the Objective Criteria Detail Score to a Customer

- The pharmacy is not surpassing their thresholds, but has been routinely purchasing very near them. The PBC frequently communicates with the pharmacy owner informing her of her accrual numbers.
- After discussing some other business matters the PBC refers to the next item on the agenda.

PBC: Do you recall when we discussed your controlled substance thresholds I mentioned that when I look in our reporting system for your accruals I also get a score called your Objective Criteria Detail score?

Pharmacist: I believe I remember. It has to do with how many days into the month we are and how much we've purchased so far, right?

PBC: No, that's a different report. That one is the reason I call you a couple times a month. The Objective Criteria Detail score has to do with the national averages we use and how your pharmacy compares to those percentages. Here let me show you.

Pharmacist: Okay, 11.98. I see that is the total of the different criteria you calculate, 2.31 plus 4.35, etc. What does that tell me?

PBC: It shows that in several areas you dispense controls above the national averages. The higher that score the higher you are above the average. For you, you are not real high in any single area but you are running somewhat high in several.

Whenever I see a customer who is on the high side of purchasing controls, I like to point out that that is an indication of risk. Knowing where you are relative to these national averages will help you identify if your pharmacy's ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions.

Looking at your report you see that the hydrocodone 10mg has the highest score. And then looking at these national averages for hydrocodone 10mg you can see that on average 33% of the hydrocodone prescriptions are the 10mg strength. The 10mg is monitored more closely because it has been shown in DEA actions against pharmacies to be more frequently diverted and abused. A higher percentage of your hydrocodone prescriptions are the 10mg strength.

Pharmacist: So, what are you suggesting I do?

PBC: Just that you should ask yourself: do you know why these products run high. I don't have a RPh or PharmD so I would not give advice, but I thought this might help. *(Hands the pharmacist the "Top 10 Questions Pharmacists Should Ask When Filling Prescriptions For Controlled Substances".)*

Pharmacist: *(Looks over the document.)* I got a copy of this before. I didn't do anything with it. I better run some reports out of my system and see how some of these doctors and patients look. I don't like the idea of being on the risky side of the DEA.

PBC: Great idea.

Pharmacist: What does this 11.98 mean as far as Cardinal? Are you calling the Feds on me?

PBC: No.

Now if you do hit a threshold for any of the controls, not just the oxy and hydro, that Objective Criteria Detail score is one of the first things our QRA analysts is going to look at. So to use their terminology you'll receive additional scrutiny.

Again these numbers are to point out that there's a pattern that should be looked into. Just like you said yourself, running reports on those controlled substance prescriptions is probably a good idea.

Maybe you'll find out that there are prescriptions there that are not worth the profit, if they are increasing the risk to you professionally and to your business.

Pharmacist: I'm going to get on this. I want you to bring me that score on a regular basis.

PBC: Absolutely.

~ ~ ~ ~ ~ ~

FACILITATOR NOTE (15 Minutes)

Review the Content

- **Proactive Communications**
  - **IMPORTANT NOTE:** Let your team know that the form **Business Change Information – submit for Threshold Review** is intended to be a starting point for a conversation with a customer about objectively verifiable information. The customer needs to present the facts and information. A sales associate must not even give the appearance of coaching a pharmacy how to circumvent our suspicious order monitoring system.
  - Refer them to the Internal Use Only document *Our Role in Preventing Prescription Drug Abuse (January 2014).*
  - A "check-the-box" form is not conducive to obtaining verifiable compelling reasons to justify a higher utilization of controlled substances.
- **Threshold Events: What happens if a threshold event does occur?**
  - Assign the **Knowledge Check – Matching: Threshold Event Occurs**
  - Give learners 5 minutes to review the section and complete the accompanying matching exercise
  - Discuss areas of concern
  - Discuss proactive use of the information in WinWatcher to avoid held orders

PROACTIVE COMMUNICATIONS (Participant Guide page 23)

QRA has provided us with guidance regarding communicating changes that occur at a pharmacy and increase their prescription volume and their controlled substance dispenses for legitimate medical needs.

How do we proactively communicate a change in a customer's business which may cause an increase in controlled substances purchases and total purchases?

The information that is needed is dependent on the pharmacy's situation. The QRA Customer Analytics team can guide you. For example: You have a customer picking up business because it has purchased the files of a nearby pharmacy that is closing. In this case, you need to obtain information to support what their anticipated total prescription volume will be. The QRA Customer Analytics team will use that new projected prescription volume for an evaluation of the customer's threshold limits. Contact one of the QRA Customer Analytics Senior Specialists or the manager, Danielle Holbrook, for assistance.

CardinalHealth

Pharmaceutical Distribution - Sales Training & Operations

SOM – QRA Process (Internal Use Only)

Business Change Information – submit for Threshold Review	
DEA number	
Customer Name	
Cardinal DC/Account Number	
Drug Family/Families Where Adjustments are Requested	
Validation for Request	*Examples:* Business model change Historical growth New information regarding pharmacy (e.g., purchased Rx files from another pharmacy) Change in distributors or change in percentage of product ordered from Cardinal Health ***Provide as much detailed information as possible. Responses must be meaningful and not general in nature such as "filling more prescriptions"***
Date of Most Recent Sales Site Visit	
Business Model	
Current Monthly Prescription Count	
Projected Monthly Prescription Count	

THRESHOLD EVENTS

What happens if a threshold event does occur?

The following explains what happens if a threshold event does occur:

- A customer orders beyond the threshold for a particular drug family
- The order is held in our electronic monitoring system, Anti-Diversion Centralization (ADC)
- The customer will receive notification by a notation on their invoice indicating the item has been held pending regulatory review.
- The PBC will receive an Anti-Diversion Centralization (ADC) System email notifying them that their customer's order is held.
- Order is reviewed by a Customer Analytics specialist who looks at the customer's objective criteria score, their order history, and any other pertinent information included within the QRA system
- The analytics team will strive for a 48 hour turnaround for a decision regarding the held order.
- If the analytics team notifies the PBC (via email) that more information is needed to make a decision, the PBC has five business days to respond with that information.
- If it is determined that an adjustment to the threshold is not warranted, the order will be cut, along with all subsequent orders over threshold for the same drug family during the customer's accrual period.
- The specialist will send an email to the PBC with the following information:
  - The order has been cut
  - The order will be reported to the DEA as suspicious.
  - There will be no change to the threshold and the current threshold limit will remain in place for that particular drug family.
  - This PBC email will only be received once per accrual period, per drug family.
- At any point during the process, the PBC is encouraged to proactively share pertinent information with QRA. Held orders may be avoided through diligent use of the information provided on the Regulatory tab within WinWatcher.

Will customer orders that are cut by QRA be reported to the DEA?

▶ Yes. Our reporting of suspicious orders does not indicate that we believe diversion is occurring. Orders are reported as suspicious if they exceed the objective measures we have put in place to monitor volume, frequency, and pattern.

(Participant Guide page 25)

Knowledge Check – Matching: Threshold Event Occurs

Match the statement to the correct answer by writing its number in front of the answer.

	STATEMENT		ANSWER
1.	This causes a held order for a controlled substance	4	Look at customer's Objective Criteria score, check order history, review other pertinent customer information in the QRA system
2.	Name of QRA's electronic order monitoring system	1	Customer orders beyond the threshold for a particular drug family
3.	PBC best practice to avoid customers' controlled substance orders being held	5	Hold all subsequent orders for the same drug family through the end of the accrual period
4.	Elements of Customer Analytics review of a held order	2	Anti-Diversion Central (ADC)
5.	Subsequent actions after decision is made that a threshold will not increase and order is cut	3	Diligent use of the information provided on the Regulatory tab within WinWatcher

FACILITATOR NOTE (10 Minutes)

NEW BUSINESS REVIEW (Participant Guide page 27)

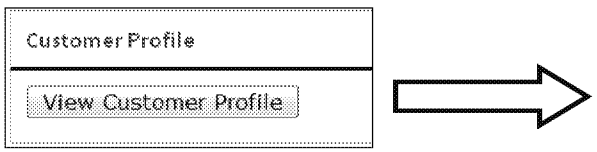
Review the content. Key call outs.

- Do a preliminary determination to see if the prospect passes the objective criteria:
  - before directing the prospect to do the online KYC new account survey.
  - before submitting a SharePoint request for account setup.
- PBCs can send the information to the Director of QRA Management – Account Setups
  - You will need all the data that goes in the fields in WinWatcher's customer profile
- One of the Objective Criteria is "percentage of all prescriptions that is oxycodone and hydrocodone prescriptions". You can see in the calculation examples in this section that this can be calculated from the total oxy dosage units plus the total hydro DUs divided by 80 (a national average).
- If a prospect is going to submit the KYC new account survey **sales should never complete the survey for them.**

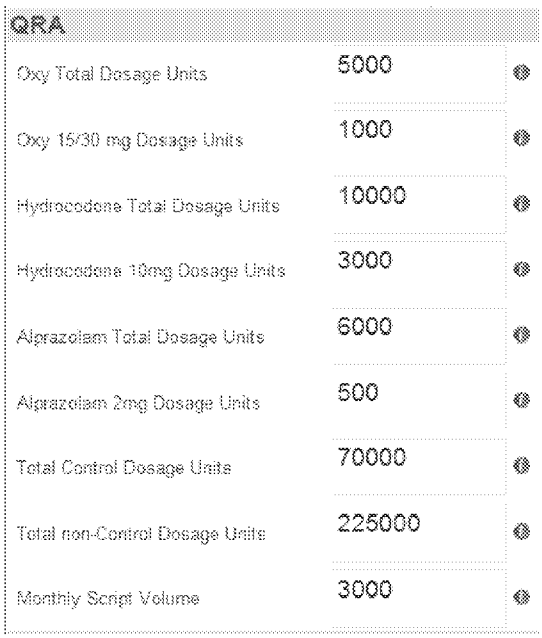
NEW BUSINESS REVIEW

ISF Procedures

Prior to instructing a prospect to submit their KYC new account survey a PBC should gather the prescription volume and dosage unit information necessary to calculate the percentages of each of the five objective criteria listed in the example below. This information will eventually need to be inputted into the KYC new account survey by the prospect. This information can be recorded in WinWatcher's myMarket Customer Profile section.



WinWatcher's myMarket Customer Profile View Button



WinWatcher's Customer Profile QRA Elements

You can then complete a preliminary review with the QRA Account Setup team by submitting your calculated Objective Criteria percentages to help better understand the viability of a prospect.

Example:

- Oxy 15/30 mg DUs / Oxy total DUs – 1000/5000 = 20%
- Hydro 10 mg DUs / Hydro total DUs – 3000/10,000 = 30%
- CS DUs / Total DUs (add CS DUs and non CS DUs together) – 70,000/295,000 = 24%
- ((5,000 total Oxy DUs plus 10,000 total Hydro DUs) divided by 80) divided by 3,000 Monthly Script Volume = 6.25%
- Alprazolam 2 mg DUs / Alprazolam total DUs – 500/6000 = 8%

The independent sales team can easily determine whether or not a SharePoint request for account setup is worth submitting based on whether or not the prospect passes the objective criteria.

Retail Independent KYC New Account Survey

If the PBC determines they will move forward with the prospect they must have the customer complete the online KYC new account survey. The hardcopy worksheet, available on the ISF Portal (Training tab, QRA section) may be used by the prospect for preliminary data collection.

The website for the Know Your Customer Survey:

[HYPERLINK "http://www.cardinalhealth.com/RIsurvey" \t "_blank"]

It is recommended that ISF associates use the SharePoint account setup site to access the most current links/versions of all documentation needed for the account set up process.

SharePoint access:

[HYPERLINK "https://nas.cardinalhealth.net/sites/ParallelWorkflow/default.aspx" \t "_blank"]

It is the responsibility of the retail independent sales team to properly communicate to the customer, and educate the customer, on the importance of providing valid and accurate data for the KYC new account survey, especially the required dosage unit information and monthly prescription volume. It is the responsibility of the customer to complete the survey accurately and completely. Sales should never complete the survey in place of a customer.

Once a pharmacy has passed the QRA new account objective criteria and due diligence review process, thresholds will be initially set using one of three baseline templates determined by the pharmacy's monthly prescription volume:

- Tier I (Small): Less than 2,778 prescriptions per month
- Tier II (Medium): 2,778 to 7,954 prescriptions per month
- Tier III (Large): Over 7,954 prescriptions per month

Once the initial baseline template has been set, then the threshold limits for the 13 drug families will be customized and set specifically for the account based on our current threshold setting methodology and in conjunction with their disclosed monthly prescription volume and their disclosed monthly dosage units from their KYC new account survey. Other controlled substance families will also be assigned threshold limits.

Monthly analysis will be completed to determine whether or not the account is purchasing the full volume of their monthly prescriptions from Cardinal Health. Cases where accounts are purchasing less than their full disclosed monthly prescription volume will have appropriate threshold adjustments made.

KNOW YOUR CUSTOMER – SALES SITE SURVEYS (Participant Guide page 29)

(WW Quiz Question #11)

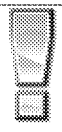
FACILITATOR NOTE (10 Minutes)

Know Your Customer – Sales Site Surveys

Review the content below. Key call outs.

- Shared responsibilities with PD Acute pertain to the retail national accounts that may have been assigned by QRA.
- PBCs are responsible for all their current customers. The Sales Manager and team mates are expected to handle mandatory surveys in the case of PTO, leave of absence etc.
- When completing comments in the survey **only input observed factual information. Never submit opinions or conclusions.**
- Doing proactive surveys, so all surveys have been completed within the last 90 days, will reduce the number mandatory surveys that may occur and disrupt sales call schedules.
- When completing surveys of retail national account locations you should not ask questions of the facility staff. Observe the facility in the same way that one of their customer's would.

QRA sales site surveys may be assigned to a member of the ISF or the PD Acute Care sales team. It is very important that you respond promptly to an email request to conduct a QRA Site Survey by using the link to WinWatcher in the email.



(#11) If you receive an email assigning a mandatory QRA sales site survey you have five (5) business days to complete the survey.

(This was increased to five business days after the initial roll out in 2013,)

Survey Request Notification Email

If a mandatory QRA site survey is required in your territory you will initially receive an email. Further actions will be accomplished in WinWatcher in both the PC and mobile versions.

Once the link in the email takes you into WinWatcher you must complete the accept/decline form. Use the drop down list and choose accept or a reason you are declining, then click the submit button.

If a survey or surveys have been accepted the pharmacy is added to the "Pending Survey Requests" list on both your WW myMobile home page menu and to your WW PC version home page.

You can use the link on the survey accept or decline form too. You may go to the survey this way if you are in the vicinity of the pharmacy when you access the accept-or-decline form.

Survey Questions

The survey asks you to answer these six questions based upon your observations of the pharmacy's public premises.

- ▶ *Were there long waiting lines at the pharmacy?*
- ▶ *Were the patients and customers at the pharmacy NOT congruent with the demographics and economics of the area?*
- ▶ *Were there significant numbers of out-of-state or out-of-area vehicles parked outside the pharmacy?*
- ▶ *Was there any evidence of illicit drug use around the pharmacy (used syringes, empty prescription containers, etc.) or suspected illicit drug transactions?*
- ▶ *Were there any mailing materials or any other evidence of an internet pharmacy?*
- ▶ *Was the investigator able to confirm any other obvious signs of diversion at the pharmacy during the site visit?*

myQRA Survey Account Detail **(WW Quiz Question #12)**

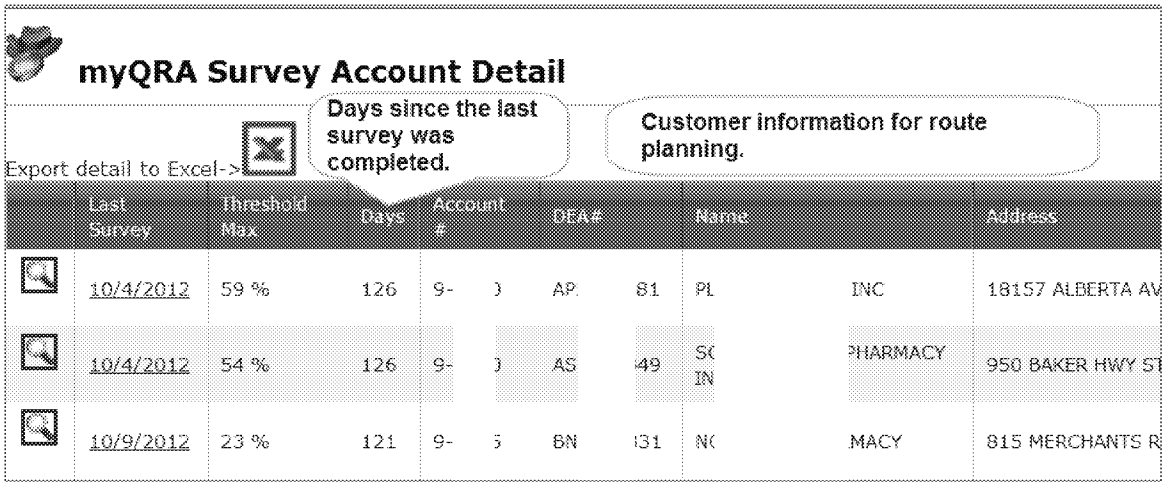
FACILITATOR NOTE (10 Minutes)

Exercise - myQRA Survey Account Detail

Have learners log into WinWatcher

- Access the QRA Survey Account Detail Report
  - Hover over myHomePage button
  - Hover over "QRA"
  - Click on "QRA Survey Account Detail"
- PBCs are to complete the questionnaire in this booklet.
  - Questions 4, 5 and 6 are rhetorical and should be used as a basis for a discussion of the need to conduct surveys proactively.

The myQRA Survey Account Detail report provides a listing of your customers in descending order by the number of days since the last site survey was submitted. It may include chain accounts assigned to you. Use this tool for route planning to efficiently conduct surveys and then redo surveys before they expire.



If you add a proactive survey (discussed below) the pharmacy will also be added to the "Pending Survey Requests" lists.

(#12) The magnifying glass icon will launch the survey in your PC or mobile WinWatcher. You will find the icon in the results from the Pharmacy Finder search, and from the mobile and PC WinWatcher Survey Account Detail report.

Log into WinWatcher • Access the QRA Survey Account Detail Report • Complete this "QRA Survey Account Detail" questionnaire
1. How many accounts on the report have not had a survey completed within the last 90 days?
2. Of the accounts without a completed survey in the last 90 days, have you made a recent sales call to any of them?
3. Of the accounts without a completed survey in the last 90 days, have you recently been within a short driving distance of any of them while on your scheduled route?
4. If any of the accounts without a completed survey in the last 90 days are retail national accounts customers, and are outside of your regular sales call route plan, what plans have you made to complete the survey(s) with the least disruption to your routine sales calls?
5. If any of the accounts without a completed survey in the last 90 days are your regular ISF customers, have you considered how a delay in resolving a Threshold Event (Held Pending Regulatory Review), because Customer Analytics is waiting for the completion of a survey to make their decision, might be disruptive to your customer's operations?
6. If you have accounts without a completed survey in the last 90 days, have you considered how the assignment of a mandatory survey due to a Threshold Event would be disruptive to your routine sales calls?

QRA COACHING OBSERVATIONS RIDE-ALONG FORM (Partic. Guide page 32)

FACILITATOR NOTE (5 Minutes)
QRA Coaching Observations Ride-Along Form • Sales Managers, use this form at your discretion. However, it is recommended that you institute observing PBC and customer QRA interactions. • Discuss with your team your plans to monitor their management and performance of their SOM responsibilities.

Periodically there may be an assessment of a PBC by the sales manager, or by a QRA associate who is traveling with them, regarding the Cardinal Health QRA and SOM processes. This will include:

- your understanding of the SOM process
- your ability to monitor and interpret QRA information with regards to their territory
- your ability to communicate with customers the Cardinal Health SOM process
- your effectiveness of related communications or required actions

A copy of a suggested coaching form is included as an appendix to this document.

This is a coaching tool when used by QRA which may be used to recommend additional training.

When used by your manager it is only one component of the overall evaluation of your territory management and your compliance with policy and procedures.

PHARMACIST CORRESPONDING RESPONSIBILITY (Participant Guide page 33)

FACILITATOR NOTE (20 Minutes)

Slide 15 – Play video 3 minute video. Note: It may take 10 to 15 seconds to begin playing.

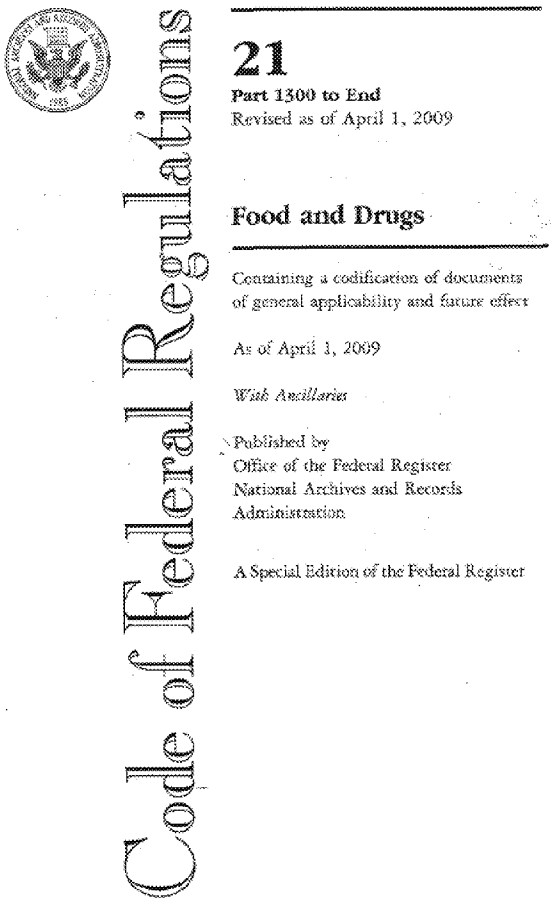
Watch for [**fill-in the blanks call-outs**] in the content.

Role Play: Pharmacist Corresponding Responsibility

- Ask a volunteer to role play a discussion with a pharmacist that feels wholesalers should not restrict a pharmacy's supply of controlled substances.
  - In the Guides is a scripted role play. Use this as a basis for discussion afterwards.
- Give the volunteer 5 minutes to review the materials and prepare.
- Have the other learners review the materials in order to discuss the role play when it is concluded.
- Have the "pharmacist" begin their part of the role play with:
  - "Wholesalers should not restrict a pharmacy's supply of controlled substances."

IMPORTANT NOTE: Based on feedback received from Sr. QRA Leadership and Legal we must proceed with great caution so we are not giving advice to licensed pharmacists, and also so that we are not asking questions and collecting information about how the pharmacist evaluates prescriptions and evaluates prescribers. As the documents on the ISF portal illustrate ("Understanding the Pharmacist's Corresponding Responsibility" and "Top 10 Questions Pharmacists Should Ask When Filling Prescriptions For Controlled Substances") our appropriate approach is limited to suggestions that the pharmacist may consider asking himself/herself when

dispensing, and that they may get asked these questions by the DEA or state regulators. The pharmacist(s) must consider these on their own and sales associates are not to collect information and are not to counsel them on these issues which pertain to the practice of pharmacy and are specific to that pharmacy, pharmacists or prescribers for whom they fill prescriptions.



Code of Federal Regulations

21

Part 1300 to End

Revised as of April 1, 2009

Food and Drugs

Containing a codification of documents of general applicability and future effect

As of April 1, 2009

With Ancillaries

Published by
Office of the Federal Register
National Archives and Records Administration

A Special Edition of the Federal Register

Drug Enforcement Administration, Justice § 1306.04

1306.12 Refilling prescriptions, issuance of multiple prescriptions.
1306.13 Partial filling of prescriptions.
1306.14 Labeling of substances and filling of prescriptions.
1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

1306.21 Requirement of prescription.
1306.22 Refilling of prescriptions.
1306.23 Partial filling of prescriptions.
1306.24 Labeling of substances and filling of prescriptions.
1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
1306.26 Dispensing without prescription.
1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7798, Apr. 24, 1971, 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[52 FR 13386, Mar. 24, 1987]

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7798, Apr. 24, 1971, as amended at 38 FR 16722, Sept. 21, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 42 FR 12986, Mar. 24, 1977]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

[36 FR 7798, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37988, Oct. 25, 1974; 76 FR 20043, June 28, 2006]

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"The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."

Discussing suspicious order monitoring and threshold limits with pharmacists may result in their raising objections. As we discussed at the beginning of this session it is important to emphasize that our methodology using these objective criteria is to help identify those

pharmacies whose ordering patterns are similar to pharmacies that have been the subject of adverse DEA actions.

The pharmacy can assess their risk by being aware of how they compare to these objective criteria.

In recent years, DEA has increased the number of [**administrative actions against**] pharmacies with a focus on ensuring that pharmacists are fulfilling their corresponding responsibility when filling controlled substance prescriptions.

Be careful that you do not appear to be giving advice about prescription dispensing to licensed pharmacists. And do not ask about or collect information about specific prescribers.

You may let the pharmacist know that the DEA and state regulators have asked pharmacists the following types of questions:

- Can the pharmacist effectively and objectively describe those processes he or she uses to help them assess whether the controlled substances they dispense to their patients are supportable? When posed with such a situation, explain to the pharmacist that they may consider evaluating the following points when they are deciding whether such volumes are supportable:
    - Whether there is a documented procedure at the pharmacy for evaluating new patients who present prescriptions for controlled substances?
    - What the pharmacist does in the event they have a new patient and are unfamiliar with the prescriber for that patient.
    - What the pharmacist does if the patient is from out of the pharmacy's geographical area? Is there a reasonable explanation for that patient to travel this distance to fill this prescription especially if there are other pharmacies closer to them?
    - What the pharmacist does if the prescriber is from out of the pharmacy's geographical area? Is there a reasonable explanation for this patient to travel that distance to see that prescriber so as to obtain this prescription?
- The pharmacist whose pharmacy dispenses above the national averages, should also consider [**assessing**] those prescribers (e.g., physicians, nurse practitioners, physician assistants, etc.) for whom they fill prescriptions. Pharmacists may want to consider the following points in making that assessment:
    - Are those prescribers that the pharmacy is filling for, the source of [**most**] of these controlled substance prescriptions dispensed? If so, is there a logical reason for this, such as the specialty of the prescriber?

- Has the pharmacist determined that his or her top controlled substance prescribers are located in the same area as the pharmacy's other top prescribers?

- Alert pharmacy customers to the importance of their assessing the legitimacy of the prescriptions they receive and simply not relying on the fact that a prescriber they may or may not recognize, wrote the prescription for a patient, and that the prescriber has a valid DEA registration.

  - Pharmacists should assess both the professional risk to their license and the risk to their business by filling prescriptions for a high controlled substance prescriber that the pharmacist may not be familiar with.,

  - The question a pharmacist should ask themselves is: "If you don't know the prescriber and their practice well, is the profit in those prescriptions worth the risk to his or her business?"

Role Play: Pharmacist Corresponding Responsibility (Participant Guide page 35)

- The pharmacist feels wholesalers should not restrict a pharmacy's supply of controlled substances, it's the pharmacists decision.

Pharmacist: Wholesalers should not restrict a pharmacy's supply of controlled substances.

PBC: We have a suspicious order monitoring program because we need to ensure the safety and security of the pharmaceutical supply chain. That's a societal obligation and it's required by the DEA.

Pharmacist: I have a valid pharmacy license and DEA certificate. I've been in this business a long time. And I'm not filling pain med scripts unless I've verified the doctor is licensed and registered to prescribe controlled substances. It's my judgment how much I need of controlled substances.

PBC: Verifying that we only ship controlled substances to customers who are properly registered with the DEA is only part of our obligation. Distributors are also required to detect suspicious orders for controlled substances and inform the DEA of suspicious orders.

Pharmacist: Suspicious orders! I'm not running a pill mill here.

PBC: The DEA defines suspicious orders as orders of unusual size, unusual patterns, and unusual frequency. They require that the quantities we distribute are reasonable and appropriate. So we go on what we know about a pharmacy and what the national averages are for dispensing controlled substances.

Pharmacist: Yeah, but if I've got a valid prescription I need the product to fill it.

PBC: Yes. As I understand it as a licensed pharmacist you have a "corresponding responsibility" to ensure that prescriptions are issued for a legitimate medical purpose by a practitioner acting within the usual course of professional practice.

Pharmacist: That sounds great but if call all the doctors second guessing their prescriptions their going to give me an earful.

PBC: Understood, but you may wish to assess if prescriptions you are filling frequently are putting you and your business at risk. The DEA has really stepped up actions to ensure pharmacist are fulfilling their corresponding responsibility.

Like, for example, they're going to want to know if you have a high ratio of dispensing controlled substances compared to "non-controls". Do you get a lot of the prescriptions for controls from a small number of prescribers? If so, is there a good reason, such as their medical specialty? Are high volume controlled substance prescribers writing for the same couple of drugs and are all their patients getting the same medications? Especially if their prescribing "cocktails" repeatedly.

Pharmacist: Yeah, uh huh.

PBC: The DEA and state regulators might also want to know about other things, like: Are a lot of your controlled substance prescriptions paid for with cash or credit card, not insurance. Are the prescribers or the patients from out of your area? Are you filling a lot of controlled substance early refills?

Those are things for you to consider, you're the licensed pharmacist. I'm just suggesting that you can examine patterns and determine if you might wish to reduce your risk.

We have to look at order patterns, size, and frequency and limit the distribution of controlled substances to amounts that are reasonable and appropriate.

Pharmacist: So if I'm doing everything right and I don't think there's any reason for the DEA to be concerned, I might as well order from a couple of places and as far as you would know I don't have a volume or pattern issues.

PBC: I certainly recommend that you do not do that. Because as I understand it, according to the DEA, purchasing the same controlled substances from more than one source is a pattern displayed by pharmacies that dispense controlled substances for other than a legitimate medical purpose.

And when Cardinal Health is aware a customer purchases the same controlled substance drug family from another distributor we may further reduce their threshold and we may refuse to sell them some or all controlled substances.

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FACILITATOR NOTE (5 Minutes)

Conclusion

- Summarize with an emphasis on
- Suspicious order monitoring is a societal obligation, not only a regulation.
- Stay informed by watching for notifications in Sales Connect and by checking the QRA Information section on the ISF Portal
- Use Customer Facing documents in conversations and studying talking points from Internal Use Only documents.

CONCLUSION

As a wholesale distributor of medications including prescription controlled substances, Cardinal Health plays an important role in preventing prescription drug abuse. A major component of our efforts to prevent prescription drug abuse is our suspicious order monitoring system.

Cardinal Health's proprietary suspicious order monitoring system is complex and sophisticated. However, at the heart of our system is the goal to answering the question: ***Does the customer's orders for controlled substances make sense based on what we know about that customer?***

Operating a system to detect suspicious orders of controlled substances is required by the DEA's regulations, and helps to protect our communities.

CardinalHealth

Pharmaceutical Distribution - Sales Training & Operations

SOM – QRA Process (Internal Use Only)

QRA Coaching Observations

Date	ISF Associate: Name/Title	QRA Representative: Name/Title

Customers Visited (*name, account number, etc.*)

A. AWARENESS FLAG REPORT

1. Associate knows how to access the report and understands it.

2. Associate demonstrated s/he prepared for sales calls using the report.

3. Associate accurately explained concerns and next steps to customer(s) on the report.

B. THRESHOLD LIMITS – MAIN AND SUB-BASE

1. Associate knows what drug families appear in WinWatcher.

2. Associate can explain sub-base code thresholds.

3. Associate demonstrated competence explaining thresholds to customer(s).

C. OBJECTIVE CRITERIA

1. Associate knows where to find the Rx script count and can explain how is calculated for each customer.

2. Associate can explain the use of the national averages for monitoring customers.

3. Associate demonstrated competence explaining objective criteria to customer(s).

D. PROACTIVE COMMUNICATIONS

1. Associate knows correct QRA department contacts for review of threshold(s).

2. Associate knows what information to request from customers for a threshold review.

3. Associate demonstrated competence explaining the request process to customer(s).

4. Associate completed Sales Site Surveys for customer(s) or assigned national account(s). Understands mandatory versus proactive Sales Site Surveys.

E. THRESHOLD EVENTS

1. Associate knows deadlines related to threshold events.

2. Associate knows correct QRA department contacts for threshold reviews.

3. Associate knows what information to request from customers in response to a threshold event.

4. Associate demonstrated competence explaining the process to customer(s).

5. Ordering Errors: Associate demonstrated competence explaining to customer(s) the process followed when threshold event is due to an ordering error.

F. NEW BUSINESS REVIEW

1. Associate knows correct QRA department contacts for New Business requests.

2. Associate knows where to direct prospects for the Know Your Customer Survey.

3. Associate demonstrated competence explaining the new account review process to prospect(s).

4. Associate acted appropriately in guiding prospect(s) through the QRA application process.

Comments

Go to Slides 16 & 17

RESOURCES (Participant Guide page 29)

Internal

Procedures and FAQs can be found on the ISF Portal at:

ISF Portal > Training tab > QRA Information

New items and updates announced in Sales Connect

Customer Facing

ISF Portal > News & Communications tab

- Pharmacist's Corresponding Responsibility White Paper
- Top 10 Questions

CardinalHealth

Pharmaceutical Distribution - Sales Training & Operations

SOM – QRA Process (Internal Use Only)

Top 10 questions

pharmacists should ask when filling prescriptions for Controlled Substances

1. **Does the prescription being presented contain all of the information required by law?**
While State laws can vary, the Federal Controlled Substances Act requires all controlled substance prescriptions to contain the full name and address of the patient, the full name, office address, and DEA number of the prescriber, the drug name, strength, dosage form, quantity, directions for use, signature and any refills if applicable.

2. **Where is the physician's office geographically located in relation to the pharmacy?**
Patients who travel significant distances to see a physician, generally do so for a reason. While isolated incidents could be innocuous, if multiple patients present prescriptions from a distant provider, it could indicate possible diversion.

3. **Where is the patient's address geographically located in relation to the pharmacy?**
Similar to traveling a great distance to visit a physician, patients who travel significant distances to visit a pharmacy generally do so for a reason. While certain geographic areas have a higher seasonal population due to tourism or vacationers, when customers repeatedly travel a significant distance to a particular pharmacy for controlled substances, this could indicate possible diversion.

4. **Is the patient paying cash for controlled substance prescriptions?**
Third party payers and insurance companies often provide a valuable service by monitoring prescriptions for usage above therapeutic needs including refills that are too soon, as well as doctor and pharmacy shopping. However, this check on the system is bypassed when no claim is submitted to the third party, and the patient pays cash.

5. **Do the majority of the patients of the prescriber receive the same medication(s), in the same quantity, with the same directions?**
When a majority of patients from one particular physician receive identical controlled substance prescription orders, it could indicate a lack of individualized treatment for these patients. This could be indicative of improper prescribing practices.

6. **Do the majority of the patients of the prescriber receive the same diagnosis?**
While it's not uncommon for physicians to specialize or even sub-specialize in a particular disease state(s), when the majority of patients have an identical diagnosis, it could be an indication that the prescriptions were not written for a legitimate medical purpose.

7. **Is the patient requesting early refills?**
Patients who present to the pharmacy requesting early refills may be taking their medication improperly. This can be either intentional abuse of the product, or unintentional due to an incomplete understanding of the prescribed directions. In either case, consultation with a pharmacist would be beneficial.

8. **Is the quantity of medication or strength prescribed unusually high?**
The quantity and strength of the medication prescribed should be appropriate for the indication. A large quantity of medication or an unusually high starting dose for an acute ailment should be cause for concern.

9. **Has the patient been prescribed a variety of different controlled substances?**
While it is sometimes necessary for patients to receive multiple controlled substances to treat a variety of conditions, certain combinations are known to be more readily abused. While isolated patients receiving these combinations may not be unusual, frequently dispensing these combinations could be indicative of diversion.

10. **Has the patient received controlled substance prescriptions from multiple providers?**
Patients that visit multiple providers for the same condition are likely not receiving the most efficient or proper care. Patients who do this and are prescribed controlled substances, may be "doctor shopping". Contacting the individual prescribers in these situations would improve the coordination of care for the patient.

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